EXHIBIT C

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No. 2022-38664

RICKY MARSHALL, Plaintiff	§	IN THE DISTRICT COURT OF
V.	§	HARRIS COUNTY, TEXAS
MEDTRONIC, INC. Defendant	§	11th _____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Ricky Marshall, plaintiff, complaining of Medtronic, Inc., defendant, and for cause of action would show as follows:

I.

This case should be governed in accordance with the Discovery Control Plan found in Rule 190 of the Texas Rules of Civil Procedure (Level 3).

II.

Ricky Marshall ("Marshall") is an individual residing in Houston, Harris County, Texas.

Medtronic, Inc., a subsidiary of Medtronic PLC ("Medtronic"), is a foreign corporation with its principle operational offices located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604. Medtronic is and has been doing business in the State of Texas. Medtronic may be served with process through its agent for process, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company 211 E. 7th Street, Suite 620, Austin, TX 78701-3136 USA.

III.

Marshall seeks to recover damages he has sustained due to a defective LVAD pump system, sometimes referred to as the HeartWare HVAD device ("HeartWare device"), manufactured and sold by Medtronic that was implanted in Marshall's chest by Saram Nathan, M.D. at Memorial Hermann Hospital, Houston, Harris County, Texas, on June 4, 2020. Marshall was discharged from

Memorial Hermann Hospital on June 29, 2020. Marshall underwent this implant surgery due to end-stage heart failure from which he was suffering. He understood at the time of his surgery the HeartWare device would assist his own circulatory system by pumping blood from his damaged heart. The Heartware device would keep Marshall alive until he was approved for and could undergo a heart transplant procedure.

IV.

Medtronic abruptly pulled its HeartWare device from the market in late May, 2021, less than a year after the device was implanted in Marshall's chest. The action undertaken by Medtronic came as a result of numerous Class I recalls and reports of patient injuries and deaths associated with the device. Prior to the implant surgery involving Marshall, there was great concern with the Medtronic HeartWare device regarding ongoing failures and a "growing body of observational clinical comparisons indicating a higher frequency of neurological adverse events, including stroke, and mortality with the Heartware device as compared to other circulatory support devices available to patients." At the time Medtronic stopped selling the HeartWare device, approximately 4,000 patients had the device implanted, including Marshall. Moreover, Medtronic advised against elective explants of the HeartWare device due to potential health risks to the patient. A patient such as Marshall was as likely to die from removal of the HeartWare device as he was if the device remained in his body.

V.

Marshall seeks damages from Medtronic, under two theories of recovery, namely:

(1) Products liability based upon:

(a) Manufacturing defect;

(b) Design defect; and

(c) Marketing defect.

(2) Negligence in the marketing and the manufacturing of the HeartWare device manufactured and sold by Medtronic, which is the subject of this lawsuit; additionally, invoking the negligence doctrine of *res ipsa loquitur*.

VI.

When it is alleged that Medtronic committed an act or practice, or by omission failed to act, it is meant that Medtronic acted or failed to act by and through its agents, servants and employees whose acts or omissions were within the scope of their authority or employment.

VII.

The cause of action giving rise to this lawsuit, that is, the claims for damages for the injuries sustained by the plaintiff as a result of Medtronic's wrongdoing, arose in Harris County, Texas.

VIII.

Medtronic was at the time of this occurrence and was the major designer, manufacturer and marketer of the HeartWare device. Additionally, at all times pertinent hereto, Medtronic was a merchant with respect to the HeartWare device within the meaning of TEX. BUS. & COM. CODE § 2.314. Medtronic was, at all times pertinent hereto, the marketer and seller of the HeartWare device.

IX.

Medtronic's decision to pull the HeartWare device from the market followed a series of Class I recalls, including three in 2021 alone, resulting in reports of 91 injuries and 15 deaths of patients with the implanted device. The Federal Drug Administration (FDA) advised healthcare providers in late May, 2021, to cease new implants of the HeartWare device system, indicating that Medtronic had "received over 100 complaints involving delay or failure to restart of the HeartWare device, including reports of 14 patient deaths and 13 cases where an explant was necessary."

Medtronic had acquired the HeartWare device was part of its $1.1 billion acquisition of HeartWare International in 2016. The device was intended to help patients suffering from heart failure pumping blood through their bodies. The system, which included an implantable pump and non-implantable components, is a Class III medical device, meaning it constitutes a high risk and can pose a significant risk of injury to patients.

Since the HeartWare device received premarket approval in November, 2012, the FDA has issued 13 Class I recalls involving multiple parts and components of the pump. Issues and malfunctions ranged from devices failing to restart to the company needing to update instructions for use and patient manuals. While some recalls predate Medtronic's acquisition, nine Class I recalls have come since Medtronic bought HeartWare.

Along with numerous recalls, the HeartWare device has received thousands of reports of patient injuries, deaths and device malfunctions in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. An analysis of MAUDE data by the watchdog group ECRI showed Medtronic's HeartWare device had a higher rate of device malfunction than comparable devices marketed by rival companies.

X.

Marshall's HeartWare device was not intended to be defective and cause unanticipated or unnecessary delays or failures to restart the pumping of blood. Such a defect was not intended to be part of the HVAD pump design or purpose. As a result, Marshall has sustained both physical and mental damages, particularly the mental stress of having an implanted device that is very unreliable and cannot be removed due to the lethal risk of explantation.

XI.

Medtronic has removed the HeartWare device from the market due to its use being associated with increased risks of mortality. Patients, such as Marshall, who have been implanted

with the device have increased morbidity, with anxiety, depression, and even post-traumatic stress response due to the device being implanted in their bodies. These consequences can lead to further functional decline in the patient, such as Marshall, and a decreased quality of life.

XII.

The HeartWare device, as manufactured, designed and marketed by Medtronic, is defective and unsafe.

The defect in the manner in which the HeartWare device was designed or manufactured at the time it left the possession of Medtronic rendered the product unreasonably dangerous and made it dangerous to an extent beyond which would be contemplated by the ordinary user of the product, including this plaintiff, with the ordinary knowledge common to the community as to the product's characteristics.

There was a design defect caused by Medtronic at the time the HeartWare device left the possession of Medtronic that rendered the product unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use.

The design and manufacturing defects in the HeartWare device that are involved in this lawsuit existed in said product while it was in the hands of Medtronic, and such defect rendered said product unfit for the ordinary purposes for which it was to have been used by the ultimate user, including this plaintiff, because of a lack of something necessary for adequacy.

There was a defect in the marketing of HeartWare device caused by Medtronic at the time it left the possession of Medtronic in that there was a failure by Medtronic to give adequate warnings of said product's dangers that were known by Medtronic or by the application of reasonably developed skill and foresight should have been known by Medtronic, or there was a failure by Medtronic to give adequate instructions to avoid such dangers, which failures rendered the HeartWare device unreasonably dangerous as marketed.

The foregoing defects, taken together, separately or in combination, constituted a producing or proximate cause or causes of the plaintiff's damages.

XIII.

Marshall did not and in the exercise of reasonable diligence could not have discovered the defects in design, manufacture and/or marketing of the HeartWare device HVAD pump system prior to the date it was implanted in his chest and the resulting injuries he sustained. Neither did he discover nor in the exercise of reasonable diligence could he have discovered the negligence of Medtronic in the design, manufacturing and/or marketing of the HeartWare device prior to the date product was implanted in his chest and the resulting injuries he sustained.

XIV.

Medtronic was negligent in designing, manufacturing and marketing the HeartWare device in question in the following respects:

(1) Medtronic was negligent in failing to properly design or compose the HeartWare device; and

(2) Medtronic was negligent in offering the HeartWare device for sale to the general public without warning the end users of the dangers associated with the HeartWare device.

Marshall cannot more specifically allege the acts and/or omissions of negligence in the manufacturing and/or design of the HeartWare device in question for the reasons that the facts in that regard are peculiarly within the knowledge of Medtronic. In this connection, Marshall would show that the design and manufacturing of the HeartWare device was within the exclusive possession and control of Medtronic. Marshall had no means of ascertaining the method and manner in which the HeartWare device was designed, tested and manufactured. The product was prescribed to and taken as recommended by plaintiff in the same condition it was in when it left the possession and control of Medtronic. The occurrence causing the injury to the plaintiff, as

described herein, was one which, in the ordinary course of events, would not have occurred without the negligence on the part of Medtronic in the design and/or manufacturing of the HeartWare device. Thus the plaintiff is entitled to invoke the negligence doctrine of *res ipsa loquitur*, thereby making Medtronic guilty of negligence in the design, manufacturing and marketing of the HeartWare device without further proof, which negligence was a proximate cause of the injuries and damages sustained by the plaintiff.

XV.

Marshall's damages exceed the jurisdictional limits of this Court. The plaintiff has been damaged in the following particulars, viz:

a. Loss of wages in the past and future;

b. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies in the past;

c. Reasonable and necessary costs of medical care and treatment including doctors, hospitals, nurses, medicine, and other services and supplies that in all reasonable probability plaintiff will suffer in the future;

d. Physical pain suffered by the plaintiff in the past;

e. Physical pain which the plaintiff will in all reasonable probability suffer in the future;

f. Mental anguish suffered by the plaintiff in the past;

g. Mental anguish which the plaintiff will in all reasonable probability suffer in the future;

h. Past impairment suffered by the plaintiff;

i. Future impairment that will be suffered by the plaintiff in all reasonably probability;

j. Past disfigurement suffered by the plaintiff; and

k. Future disfigurement that will be suffered by the plaintiff.

As a result of such particulars, Marshall has been damaged in an amount in excess of the minimum jurisdictional limits of this Court.

XVI.

Marshall is entitled to recover his actual damages, prejudgment interest, and exemplary or punitive damages as a result of the above allegations of liability and damages. The assessment of any exemplary and/or punitive damages should include evidence of and consideration of reasonable attorney's fees.

WHEREFORE, PREMISES CONSIDERED, Ricky Marshall, plaintiff, requests Medtronic, Inc., defendant, be cited to appear and answer, and that upon final trial, they have:

a. Judgment against Medtronic Inc. for ONE MILLION AND NO/100 DOLLARS ($1,000,000.00);

b. Pre-judgment and post-judgment interest on damages assessed against the defendant at the prescribed legal rate;

c. Costs of court; and

d. Such other and further relief, at law or in equity, to which they may be justly entitled.

Respectfully submitted,

THE TRIMBLE FIRM, P.L.L.C.

/s/ Dale L. Trimble

By_____

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